

REMARKS

Claims 2-5, 9-12, 14-15, 23-27, 29-30, 32-33, 37-41, 43-44, 47-53, and 55-56 are pending and under examination. Applicants have amended the phrase “one or markers” to “one or more markers” in claims 10, 25, 37, and 49. That amendment corrects a typographical error. Applicants have amended claims 9, 23, 47, 48, and 55 to recite “wherein the genetically modified cell strains are separately grown and imaged.” That amendment is supported, for example, at page 6, lines 12-14, and at page 8, lines 3-4. The foregoing amendments add no new matter. Applicants respectfully request reconsideration of the rejections set forth in the Office Action mailed on June 6, 2005.

Information Disclosure Statement (“IDS”)

The Examiner has not considered all the documents cited in the IDS filed on 3/7/2005. The Examiner contends that “an original application or a copy of an office action from a co-pending application which has not yet matured into an issued patent or otherwise become publicly available is not a proper document to be listed on a PTO 1449 under 37 C.F.R. 1.98(a)” (Office Action at page 2). Applicants respectfully assert that 37 C.F.R. 1.98(a) does not provide any basis for that contention. 37 C.F.R. 1.98(a) recites that an IDS may include “[a] list of all patents, publications, applications, or other information” 37 C.F.R. 1.98(a)(1) (emphasis added). The original application and copies of office actions from co-pending applications qualify as “other information.” Thus, those documents were properly submitted in the IDS filed 3/7/2005. Accordingly, Applicants respectfully request the Examiner to consider those documents.

Rejections under 35 U.S.C. § 112, paragraph 1

The Examiner rejected claims 4 and 5 under § 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the enablement requirement (Office Action at page 3). Specifically, the Examiner stated that those claims were rejected because “they recite deleting every one of the non-essential genes in a parental stain, which is unpredictable as being directed to a complex and undefined result for complex organism, as set forth in the previous office action mailed 12/9/2004” (Office Action at page 3).

“The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” M.P.E.P. § 2164.01 (quoting *United States v. Telectronics, Inc.*, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988)). “Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is ‘undue,’ not ‘experimentation.’” *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988); see also M.P.E.P. § 2164.01.

Claim 4 recites “wherein the collection of genetically modified cell strains contains a deletion mutation for each non-essential gene in the parent strain.” Applicants assert that claim 4 is enabled based on the disclosure coupled with information known in the art. The specification indicates at page 1, lines 21-27, that “[t]he entire yeast genome has now been mapped and sequenced. [The genome of *Saccharomyces cerevisiae*] has been analyzed and systematically modified by the *Saccharomyces cerevisiae* Deletion Consortium to yield a complete set of congenic deletion mutations.” Further, the results of Winzeler *et al.* “show that thousands of

deletants can be systematically made once the sequence of a genome is known.”

Winzeler *et al.*, *Science* 285: 901-905 (Aug. 6, 1999) (cited in the present Office Action), at page 904, col. 2 . The yeast genome is completely sequenced, and a complete set of yeast deletion mutants has and can be systematically made as indicated above.

Applicants assert that establishing which genes are non-essential would merely require the routine screening of the deletion mutants to see which deletion mutants are viable.

Applicants remind the Examiner that when evaluating enablement, “a considerable amount of experimentation is permissible, if it is merely routine.” *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

Based on the disclosure of the specification coupled with the information known in the art, one skilled in the art can practice the method of claim 4 without undue experimentation. Therefore, claim 4 is enabled. Claim 5 ultimately depends from claim 4. Thus, that claim is also enabled. Applicants therefore respectfully request that the rejection of claims 4 and 5 under 35 U.S.C. 112, first paragraph, be withdrawn.

Rejections under 35 U.S.C. § 103

Examiner rejected claims 2-4, 9-12, 14-15, 23-27, 29-30, 32-41, 43-44, 47-53, and 55-56 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ashby *et al.* (U.S. Patent No. 6,518,035) in view of Giuliano *et al.* (U.S. Patent No. 6,416,959) and Price *et al.* (U.S. Patent No. 5,548,661) (Office Action at page 4). Applicants respectfully traverse.

To establish a *prima facie* case of obviousness, it is the Examiner’s burden to show that the cited references would have taught or suggested all the elements of a claimed invention. See M.P.E.P. § 2143. The Examiner must also show “some

suggestion or motivation” to combine the references. See *id.* Finally, the Examiner must show that there would have been a reasonable expectation of success. See *id.* Failure to establish any one of these three requirements precludes a finding of a *prima facie* case of obviousness.

Solely to expedite prosecution and without acquiescing to the Examiner's arguments, Applicants have amended claims 9, 23, 47, 48, and 55 to recite “wherein the genetically modified cell strains are separately grown and imaged.” In contrast, Ashby teaches a co-culture assay in which at least two populations of cells are grown in the same culture and imaged together. See Ashby at col. 5, lines 52-58; col. 7, lines 28-39. Thus, Ashby would have failed to teach or suggest genetically modified cell strains that are separately grown and imaged, according to claims 9, 23, 47, 48, and 55. Giuliano and Price do not cure this deficiency as neither reference would have taught or suggested analyzing a collection of genetically modified cell strains, wherein the strains are separately grown and imaged.

For at least the foregoing reason, Ashby in view of Giuliano and Price would have failed to render obvious claims 9, 23, 47, 48, and 55. Claims 2-4, 10-12, 14-15, 24-27, 29-30, 32-41, 43-44, 49-53, and 56 ultimately depend from claims 9, 23, 47, 48, and 55. Thus, those claims are nonobvious. Applicants request withdrawal of the rejection of claims 2-4, 9-12, 14-15, 23-27, 29-30, 32-41, 43-44, 47-53, and 55-56 under 35 U.S.C. § 103(a).

The Examiner further rejected claim 5 as allegedly being unpatentable over Ashby *et al.* (U.S. Patent No. 6,518,035) in view of Giuliano *et al.* (U.S. Patent No. 6,416,959) and Price *et al.* (U.S. Patent No. 5,548,661) and further in view of Winzeler

et al. (*Science* 285: 901-906 (Aug. 6, 1999) (Office Action at page 8). Applicants respectfully traverse.

Claim 5 ultimately depends from claim 55 and thus includes all the elements of that claim. Claim 5 further recites “wherein the collection of genetically modified cell strains includes the deletion mutants provided by the *Saccharomyces cerevisiae* Deletion Consortium.” For at least the same reason discussed above for claim 55, Ashby, Giuliano, and Price would not have taught or suggested claim 5. Winzeler merely discloses a collection of deletion mutants and thus fails to cure the deficiencies of Ashby, Giuliano, and Price. Thus, claim 5 is not obvious over Ashby in view of Giuliano and Price and further in view of Winzeler. Applicants request withdrawal of the rejection of claim 5 under 35 U.S.C. § 103(a).

Conclusion

Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the application. In the event that the Examiner does not find the claims allowable, Applicants request that the Examiner contact the undersigned at (650) 849-6778 to set up an interview.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

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